PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
4239-64453		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US03/01784	21 January 2003 (21.01.2003)	18 January 2002 (18.01.2002)

International Patent Classification (IPC) or national classification and IPC

IPC(7): C12P 19/34; C12Q 1/68; G01N 33/50 and US Cl.: 435/91.1, 6; 702/19

Applicant

THE GOVERNMENT OF THE UNITED STATES OF AMERICA AS

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
02 July 2003 (02.07.2003)	14 April 2004 (14.04.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer James Martinell Telephone No. (703) 308-0196

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/01784

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-29 as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the claims:
pages 30 and 31 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☒ the drawings:
pages 1-18 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*
*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/01784

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims	NONE	YES
	Claims	1-12	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-12	NO
Industrial Applicability (IA)	Claims	1-12	YES
	Claims	NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-11 lack novelty under PCT Article 33(2) as being anticipated by either one of Balagurunathan et al or Duggan et al . The signal model of Balagurunathan et al is embraced by the methods of the claims (*e.g.*, see the abstract). Duggan et al discloses the claimed methods (*e.g.*, see abstract and Figures 1 and 2).

Claims 1-12 lack novelty under PCT Article 33(2) as being anticipated by Chen et al. The model of Chen et al is embraced by the methods claimed in claims 1-11 (*e.g.*, see the abstract of Chen et al and sections 3-5 of Chen et al). In addition, Chen et al discloses the use of computer readable media in conjunction with the microarray system (*e.g.*, see figure 1 of Chen et al).

Claim 12 lacks an inventive step under PCT Article 33(3) as being obvious over either one of Balagurunathan et al or Duggan et al in view of Chen et al. Each of Balagurunathan et al or Duggan et al is discussed above. Chen et al discloses the use of computer readable media in conjunction with the microarray system. To use the computer system of Chen et al in the microarray system of either one of Balagurunathan et al or Duggan et al would not involve an inventive step.

Claims 1-12 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

AMENDED CLAIMS

[received by the International Bureau on 07 October 2003 (07.10.2003); original claims 1 amended; new claims 3-23 added (5 pages)]

WHAT IS CLAIMED IS:

1. A computer-implemented method of generating a simulated microarray image, the method comprising:

receiving a plurality of simulation parameters; and

generating the simulated microarray image based at least on the simulation parameters.

2. A computer-readable medium comprising computer-executable instructions for performing the method of claim 1.

3. The computer-implemented method of claim 1 wherein the simulated microarray image is associated with known values, the method further comprising:

analyzing the simulated microarray image via a microarray imaging procedure, the analyzing comprising calculating observed values; and

comparing the known values with the observed values to benchmark the microarray imaging procedure.

4. The computer-implemented method of claim 3 wherein:

the known values comprise signal intensities;

the observed values comprise signal intensities; and

the comparing compares the signal intensities of the known values with the signal intensities of the observed values.

5. The computer-implemented method of claim 1 wherein the simulated microarray image simulates random perturbations in array preparation, printing, and scanning.

6. The computer-implemented method of claim 1 wherein the simulated microarray image simulates background noise.

7. The computer-implemented method of claim 1 wherein the simulated microarray image simulates radius variation of cDNA deposition spots.

8. The computer-implemented method of claim 1 wherein the simulated microarray image simulates spot drift of cDNA deposition spots.

9. The computer-implemented method of claim 1 wherein the simulated microarray image simulates center core variation of cDNA deposition spots.

10. The computer-implemented method of claim 1 wherein the simulated microarray image simulates chord removal of cDNA deposition spots.

11. The computer-implemented method of claim 1 wherein the simulated microarray image simulates edge noise of cDNA deposition spots.

12. The computer-implemented method of claim 1 wherein the simulated microarray image simulates edge enhancement of cDNA deposition spots.

13. The computer-implemented method of claim 1 wherein the simulated microarray image simulates signal intensity.

14. The computer-implemented method of claim 1 wherein the simulated microarray image simulates channel conditioning.

15. The computer-implemented method of claim 1 wherein the simulated microarray image simulates spike noise.

16. The computer-implemented method of claim 1 wherein the simulated microarray image simulates scratch noise.

17. The computer-implemented method of claim 1 wherein the simulated microarray image simulates snake noise.

18. The computer-implemented method of claim 1 wherein the simulated microarray image simulates smoothing.

19. The computer-implemented method of claim 1 wherein the generating comprises randomization at a spot level of the simulated microarray image.

20. The computer-implemented method of claim 1 wherein the generating comprises randomization at a block level of the simulated microarray image.

21. The computer-implemented method of claim 1 wherein the generating comprises randomization at an array level of the simulated microarray image.

22. A software system for generating a simulated microarray image, the system comprising:

simulation parameters; and

a simulated microarray image generator operable to generate a simulated microarray image based at least on the simulation parameters.

23. A software system for generating a simulated microarray image, the system comprising:

means for storing simulation parameters; and

means for generating a simulated microarray image based at least on the simulation parameters.

24. A method comprising:

generating a simulated microarray image based on simulation parameters, wherein the simulated microarray image is associated with known values; and

analyzing the simulated microarray image via a microarray imaging procedure, the analyzing comprising calculating observed values.

25. A computer-readable medium having computer-executable instructions for performing the method of claim 24.

26. The method of claim 24 further comprising:

comparing the known values with the observed values to benchmark the microarray imaging procedure.

27. The method of claim 28 further comprising:

generating a rating based on results of the comparing, wherein the rating indicates effectiveness of the microarray imaging procedure.

28. The method of claim 24 wherein the values comprise spot intensity values.

29. The method of claim 24 wherein the generating comprises simulating a fluorescent background level for the simulated microarray image.

30. The method of claim 24 wherein the generating comprises simulating spots for the simulated microarray image.

31. The method of claim 24 wherein the generating comprises simulating post-processing phenomena for the simulated microarray image.

32. A method for simulating a microarray, comprising:

defining a plurality of parameters;

generating a microarray according to the parameters using an imaging procedure;

comparing the microarray to a known value; and

evaluating the imaging procedure in response to the comparison.

33. A computer-readable medium having computer-executable instructions for performing the method of claim 32.